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Health Care

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# CMS Proposes Amendments to Payments Furnished from Provider-Based Departments

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As part of the CY 2017 proposed Hospital Outpatient Prospective Payment System rules (OPPS) the Centers for Medicare and Medicaid Services (CMS) released the long awaited proposed payment changes for items and services furnished from off-campus provider-based hospital outpatient departments (Proposed Rule). CMS' Proposed Rule can be found here.

These proposed payment changes were necessitated by Congress's passage of Section 603 of the Bipartisan Budget Act of 2015 (Section 603) last fall and evince CMS' exceptionally narrow interpretation of that provision and threaten the ability of hospital providers to continue growing and expanding existing outpatient service capabilities, thereby constraining the services available to Medicare beneficiaries. Reshaping the Proposed Rule will take a concerted stakeholder effort, so we encourage all hospitals and interested stakeholders to submit comments to CMS. Moreover, to the extent you have any projects under development that would be impacted by the Proposed Rule, if finalized, or projects that are on hold as a result of Section 603, we strongly encourage you to reach out to Polsinelli so that we may assist you in developing a strategy to approach CMS and/or Congressional representatives to ensure your concerns are heard.

The Proposed Rule focuses on the implementation of Section 603 and does not address other downstream implications flowing from the Proposed Rule (e.g., impact on 340B status, cost reporting, etc.) or other areas of long-standing uncertainty, such as space and time-sharing. Within the confines of the Proposed Rule, CMS focused its efforts on developing and explaining its rationale for the proposed regulations surrounding the provision and billing of items and services from excepted and nonexcepted provider-based hospital outpatient departments (PBDs). An excepted PBD includes those off-campus PBDs in existence and billing for services prior to November 2, 2015, or otherwise exempted from Section 603 (e.g., dedicated emergency departments), while a nonexcepted PBD includes those off-campus PBDs that came into existence and billed for services on or after November 2, 2015.

## Major Themes of the Proposed Rules

The Proposed Rule contains six major themes:

1. **Exception for Items and Services Furnished in a Dedicated Emergency Department**
   Under the exception for items and services furnished in a dedicated emergency department (as defined at 42 C.F.R. 489.24(b)), CMS indicates that "all services furnished in an ED" regardless whether they are emergency services, would continue to be paid under OPPS. It is unclear from the Proposed Rule itself just how broadly CMS will interpret this exception. For example, if the dedicated emergency department qualifies as such under 42 C.F.R. § 489.24(b) by providing at least one third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring an appointment, it is unclear whether the dedicated emergency department will also be able to provide scheduled outpatient services for the diagnosis or treatment of non-emergent patients.

2. **Definition of the term "Department of a Provider"**
   CMS did not seek to formally change the definition of the term, "Department of a Provider." However, CMS did clearly indicate that the term includes both the specific physical facility constituting the provider-based department, as well as the personnel and equipment needed to deliver services at that facility. While the existing regulatory language remains unchanged, this could be seen as a slight departure from prior guidance issued by CMS indicating that the focus of the provider-based rules was aimed at the specific physical facility without emphasis on the personnel or equipment, or even the specific services delivered therein. The ramifications of this departure are readily seen in CMS' proposals relating to the relocation and/or expansion of excepted PBDs, discussed below.

3. **Definition of the Term "Campus"**
   CMS did not seek to formally change the definition of the term "campus." However, because Section 603 extended the reach of the term "campus" to include not only the area within 250 yards from a main provider, but also within 250 yards from a remote hospital location, CMS took the opportunity to propose that the distance used to measure the 250 yards from a remote location of a hospital should be measured in a straight line by use of surveyor reports or other appropriate documentation from any point of a remote location. Interestingly, CMS does not discuss whether the existing flexibility to exceed the 250-yards on a case-by-case basis also applies to remote hospital locations, or whether it will strictly construe the 250-yard limitation. Moreover, CMS makes no mention of how to measure the 250-yard distance from the main provider or where on a provider-based department (e.g., a PBD within an MOB) the straight line should end. MACs have varying views on how to measure this distance—some interpretations are very limiting and others are more constructive—and the Proposed Rule does not appear to provide additional guidance.

4. **Relocation of Off-Campus PBDs**
   With regard to excepted off-campus provider-based departments in existence prior to November 2, 2015, CMS proposes to preclude the relocation of such departments for any reason. Specifically, CMS indicates that if an existing, excepted PBD relocates to another location, the exception would be forever lost. In making this proposal, CMS indicated that the exception under Section 603 runs only to the specific physical location included on the hospital's Medicare enrollment profile (as of November 1, 2015), as well as the items and services furnished and billed at that specific location. The physical location is defined by the street address, including the suite or unit number, identified on the hospital's 855A. Accordingly, any movement of that PBD from that specific address equates to a loss of the excepted status. Importantly, this includes movement of an excepted PBD from one suite/unit in the same building to another suite/unit in that same building and the expansion of one suite/unit within a building to encompass a neighboring suite. While CMS takes a hardline approach to proposed relocations of existing excepted PBDs, CMS is soliciting comments and proposals to allow for a clearly defined, limited exception for necessary relocations due to a natural disaster or other extraordinary circumstances—discussed in greater detail below.

5. **Expansion of Services Offered at Excepted Off Campus PBDs**
   CMS proposes to prohibit hospitals from expanding the

services offered from an otherwise excepted PBD and billing for those services under OPPS, unless those services are part of the same "clinical family of services." CMS has proposed 19 such clinical families of services based on APCs with HCPCs codes mapped to each. In the event expanded services are not part of the same clinical family of services, such services are non-excepted and must be billed under the Medicare Physician Fee Schedule (MPFS), if at all. As a result of this proposal, the services furnished (or at least that clinical family of services) in excepted PBDs are effectively frozen in time to those services that existed as of November 2, 2015, with little exception. Thus, if an existing, excepted PBD provided and billed for only oncology services as November 2, 2015, it could expand and bill for the types of oncology services it provided under OPPS (as long as they were within the CMS-clinical family of services), but it could not expand those services to include unrelated advanced imaging services and expect to bill for them under OPPS. Any such additional services that do not fall within the excepted clinical family of services would have to be billed under the MPFS or other applicable fee schedule.

6. **Change of Ownership (CHOW) and Excepted Status**
CMS proposes to allow the excepted status of an off-campus PBD to be transferred to a new owner as long as: (1) ownership of the entirety of the main provider hospital facility to which the excepted off-campus PBD attaches is transferred to the new owner; and (2) the new owner accepts the Medicare provider agreement of the main provider – which carries with it successor liability. Not surprisingly, if in the context of the change of ownership, the new owner rejects assignment of the provider agreement, or the provider agreement is otherwise voluntarily terminated, the excepted off-campus PBDs lose their excepted status. CMS also made clear that, under the proposal, individual excepted off-campus PBDs cannot be transferred from one hospital to another and still maintain excepted status.

7. **Payment for Items and Services Furnished from Nonexcepted Off-Campus PBDs**
CMS readily admitted in the Proposed Rule that it does not have a mechanism to compensate hospitals under an "applicable payment system" as required by Section 603 other than the OPPS for items and services furnished from nonexcepted off-campus PBDs and cannot develop such a mechanism by January 1, 2017 – the date specified in Section 603 of the Bipartisan Budget Act. As a result, CMS proposes delaying the implementation of such a mechanism until CY 2018. In the interim, CMS gives hospitals three choices: (1) don't bill for CY 2017 for ancillary/technical items and services furnished in nonexcepted off-campus PBDs; (2) enter into some "arrangement" with physicians furnishing services in the nonexcepted PBD where the physician bills for and is paid for all nonexcepted services under the MPFS (and presumably, the physician makes payment to the hospital for the hospital's ancillary/technical services; or (3) enroll and submit claims as another freestanding facility or supplier type payable under the MPFS or Clinical Lab Fee Schedule (CLFS), such as a physician practice, IDTF, ASC or other supplier. At the same time, CMS directs physicians to begin billing for their professional services under the MPFS at the nonfacility rate instead of the facility rate. This proposal clearly creates a multitude of problems, both relational and under a variety of regulations for which CMS has solicited specific comments.

## 340B Implications of the Proposed Rule

Currently, PBD 340B drug pricing program eligibility is based on a hospital's ability to demonstrate that the PBD is a reimbursable cost center (Worksheets A/C, lines 50-118) on the hospital's most recently filed Medicare cost report. Because CMS did not present permanent and clear guidelines on how hospitals are to seek reimbursement for services provided in nonexempt PBDs, it is unclear whether nonexempt PBDs will qualify for 340B under the current reimburseable cost center criteria. However, CMS appears inclined to continuing to recognize nonexcepted PBDs as hospital departments that will simply be paid under an alternative payment system. This could positively impact 340B eligibility, but we encourage providers to submit comments to ensure that 340B eligibility is maintained.

## Solicitation for Comments

In connection with the Proposed Rule, CMS solicited interested stakeholders for a variety of comments. Comments are due no later than 500PM EST on September 6,

2016. We strongly encourage all hospitals and other interested stakeholders to submit comments. The Proposed Rules are already under heavy fire from the American Hospital Association, the Federation of American Hospitals and America's Essential Hospitals. However, CMS needs to hear comments from individual providers as well. The more comments CMS receives about the Proposed Rules and the impact it has on individual hospitals and interested stakeholders, the more likely CMS is to reconsider its initial proposals.

The comments CMS specifically solicited include the following, though comments need not be limited to these areas:

1. ***Information needed to identify nonexcepted PBDs for purposes of Section 603.*** CMS solicits public comments on the type of information necessary to identify nonexcepted PBDs for purposes of Section 603 of the Bipartisan Budget Act, but is not proposing to collect such information in CY 2017.

2. ***Development of a relocation exception process.*** CMS solicits public comments on whether it should develop a "clearly defined, limited relocation exception process," for hospitals struck by a natural disaster or any other extraordinary circumstances beyond the hospital's control that would allow off-campus PBDs to relocate and maintain their excepted status.

3. ***Development of a specific timeframe to allow an expansion to a related "clinical family of services."*** CMS solicits comments whether it should develop a timeline within which an otherwise excepted PBD provided and billed for services that it seeks to expand into. In other words, whether CMS should develop a rule that in order to expand services in a related "clinical family of services" the excepted PBD had to provide and bill for such services within a year or more before November 2, 2015.

4. ***Proposed categories of proposed clinical families of services.*** CMS is seeking comments on the proposed 19 categories of clinical families of services, and the proposal not to limit the volume of services furnished within a clinical family of services that the hospital was billing prior to November 2, 2015.

5. ***Changes of Ownership.*** CMS is seeking comments regarding its proposal with respect to the transfer of excepted PBDs status in connection with a CHOW.

6. ***Data Collection.*** CMS is seeking comments on whether to require hospitals to self-report all individually excepted off-campus PBD locations, the date that each began billing and the clinical family of services billed prior to November 2, 2015.

7. ***Changes to enrollment forms, claim forms, hospital cost reports and hospital operations necessary to implement a mechanism to bill for items and services from nonexcepted PBDs.*** CMS solicits comments on any changes to enrollment forms, claim forms, the hospital cost report, or hospital operations to allow a nonexcepted PBD to bill for items and services under MPFS or another payment system other than OPPS in a way that allows for payment accuracy and that minimizes the burden on providers and beneficiaries.

8. ***Impact of other existing rules on payment for items and services furnished from a nonexcepted PBD.*** CMS is soliciting comments regarding the impact of any other billing and claims submission rules, the fraud and abuse laws and other statutory and regulatory provisions that may impact the payment proposals for items and services furnished from nonexcepted PBDs. More specifically, CMS solicits comments on the limitations and impact the reassignment rules, anti-markup rule, physician self-referral (or Stark) laws, and the Federal anti-kickback statute may have on such proposals. These concerns would most likely come about for non-employed physicians billing for services performed in hospital space, but for which the hospital can no longer bill under the OPPS. The non-employed physician would receive the overhead component of the payment and then have to transfer that portion of the payment back to the hospital.

9. ***Billing for items and services furnished from a nonexcepted PBD on the CMS 1500 claim form.*** CMS solicits comments regarding whether an nonexcepted off-campus PBD should be allowed to bill for items and services on the CMS 1500 claim form and receive payment under the MPFS, provided the PBD meets all

applicable MPFS requirements. In considering this proposal, CMS indicates the PBD would continue to be considered part of the hospital and would have to continue to meet the hospital conditions of participation and provider-based rules, in addition to the applicable MPFS requirements. Presumably, this is in effort to alleviate tensions for filing of cost reports and claiming reimbursement for outpatient drugs under the 340B program, especially considering CMS also seeks comments regarding the impact such a proposal would have on how costs associated with furnishing such services might be reflected on the hospital's cost report.

## Potential Congressional Action

Immediately following enactment of the Bipartisan Budget Act of 2015 hospital associations and individual institutions pressed Congress for relief from Section 603 of the law. That Section was included at the insistence of the White House. The President's FY 2016 budget submission included a proposal calling for services furnished from off-campus hospital outpatient departments to be reimbursed at the same level as equivalent services reimbursed under the MPFS, as originally suggested by the Medicare Payment Advisory Commission (MedPAC).

In response to the hospital advocacy, the House of Representatives passed H.R. 5273, the "Helping Hospitals Improve Patient Care Act of 2016," by voice vote on June 7, 2016. The law excluded certain off-campus PBDs from specified rules that mandated lower Medicare payments. Specifically, the exclusion applies to: (1) cancer hospitals in off-campus PBDs, and (2) mid-build PBDs. A "mid-build" PBD is one for which the provider had, before a certain date, a binding written agreement with an outside party for construction.

In the Senate, H.R. 5273 was referred to the Committee on Finance. The Committee views H.R. 5273 as a House-passed product. However, it is reviewing a number of Medicare policy matters that could be considered before the end of the year.

The American Hospital Association, America's Essential Hospitals, and the Federation of American Hospitals have communicated concerns to Congress about the Proposed Rule and in particular implementation of Section 603.

Congress will recess for the summer on July 15th and return after Labor Day. It will go out again in either late September or early October for the elections. It is expected that the Congress will convene a lame duck session following the elections during which time a Medicare bill might be considered. The success of relief legislation will depend upon the ability of the two parties to agree on a possible remedy and the budgetary costs of such relief provisions.

## For More Information

For questions regarding this information, please contact the author, a member of Polsinelli's Health Care practice, or your Polsinelli attorney.


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